

Remarks

Claims 59-68 currently are pending. Consideration of the arguments below is respectfully requested.

I. Rejection of Claims 64-68 under 35 U.S.C § 101

Claims 64-68 were rejected as allegedly claiming the same invention as that of claims 10-17 of prior U.S. Patent No. 6,660,247 (the '247 patent). This rejection is traversed.

A statutory-type double patenting rejection under 35 U.S.C. § 101 is proper when the claims being considered are directed to the same invention. M.P.E.P. § 804(II)(A). When comparing two claims, the test for statutory-type double patenting is “whether one of the claims could be literally infringed without literally infringing the other.” *In re Vogel*, 164 USPQ 619, 622 (CCPA 1970). If so, then statutory-type double patenting does not exist.

No single claim among claims 10-17 of the '247 patent includes all of the limitations in any one of the present claims 64-68. For example, none of claims 10-17 of the '247 patent recite both that the polymeric compound is an aqueous polymeric solution when injected into a specific locus in a human body and that the polymeric compound is a gel in the specific locus in the human body when exposed to the critical minimum values of at least two environmental stimuli. Embodiments that do not satisfy these limitations potentially fall within the scope of claims 10-17 of the '247 patent, but not within the scope of present claims 64-68. Therefore, statutory-type double patenting does not exist and the rejection should be withdrawn.

II. Rejection of Claims 59-63 under Obviousness-Type Double Patenting

Claims 59-63 are allegedly unpatentable over claims 18-31 of the '247 patent based on an obviousness-type double patenting rejection. This rejection is traversed.

Claims 59-63 recite embodiments of a method for sterilizing a mammal using a polymeric compound. None of the claims of the '247 patent recite sterilization of a mammal. As the Examiner noted, claims 22 and 23 of the '247 patent recite injecting the polymeric compound in solution form into a specific locus in a human body and injecting the polymeric compound in solution form to achieve therapeutic embolization, respectively. The term “therapeutic embolization,” as recited in claim 23 of the '247 patent, is non-specific and

encompasses a broad range of medical procedures. Accordingly, the obviousness-type double patenting rejection should be withdrawn.

III. Rejection of Claims 59-68 under 35 U.S.C § 112, First Paragraph

Claims 59-68 were rejected as allegedly lacking enablement. This rejection is traversed.

The Examiner alleges that the disclosure fails to include a sufficient number of working examples. The disclosure, however, recites numerous working examples, including several varieties of each of linear random, block and graft copolymers of a [meth-]acrylamide derivative and a hydrophilic comonomer. Genus claims typically are enabled if the disclosure includes representative examples and a statement applicable to the genus as a whole. M.P.E.P. § 2164.01. The representative polymeric compound examples in the present application and the compounds claimed are linked by the fact that they gel only upon exposure to critical minimum values of at least two environmental stimuli.

In addition to numerous examples, the disclosure provides a person of ordinary skill in the art with the information and motivation necessary to formulate additional multiple-stimulus polymeric compounds. As the Examiner noted, the level of skill of a person of ordinary skill in the art in this technical area is particularly high. Office Action of July 27, 2004, at page 6. Based on the extensive description and the number of examples in the application, no undue experimentation would be required for the skilled artisan to extrapolate from the disclosed compounds. Accordingly, the rejection under 35 U.S.C § 112, first paragraph should be withdrawn.

IV. Rejection of Claims 59-68 under 35 U.S.C § 112, Second Paragraph

Claims 59-68 were rejected under 35 U.S.C § 112, second paragraph as allegedly being indefinite. This rejection is traversed.

The Examiner alleges that the “claims as written read on various polymeric compounds and combinations thereof.” Specific polymeric compounds do not need to be recited in the claims to satisfy the second paragraph of 35 U.S.C. §112. The M.P.E.P. is clear that “breadth of a claim is not to be equated with indefiniteness.” M.P.E.P. § 2173.04. Nonetheless, the claims define the polymeric compounds by reciting gellation “upon exposure to the critical minimum values of the at least two environmental stimuli.” There is no single term in claims 59-68 that

does not have a clear meaning. The rejection under 35 U.S.C § 112, second paragraph should be withdrawn.

V. Rejection of Claims 64, 65, 67 and 68 over Goupil et al. - 35 U.S.C. § 103(a)

Claims 64, 65, 67 and 68 were rejected as allegedly being obvious over U.S. Patent No. 6,652,883 (the ‘883 patent). This rejection is traversed.

The ‘883 patent discloses a composition for use in tissue bulking and coating. The Examiner alleges that “transformation of the solution to gel is obvious because [the ‘883 patent discloses] that changes [in conditions] such as temperature and pH result in a transformation of the solution.” In contrast to the ‘883 patent, claims 64, 65, 67 and 68 recite a polymeric compound that is a gel upon exposure to critical minimum values of **at least two** environmental stimuli.

Not only does the ‘883 patent fail to disclose gellation, it also fails to disclose transformation of the composition in response to more than one environmental stimuli. The ‘883 patent plainly states that the composition may degrade “in response to **an** applied condition, such as a change in temperature **or** pH.” Column 2, lines 49-53 (emphasis added). Nowhere does it teach that any transformation can be made dependent on two or more environmental stimuli, let alone exposure to critical minimum values of two or more environmental stimuli, as recited in claims 64, 65, 67 and 68. Accordingly, this rejection should be withdrawn.

VI. Dependent Claims

All rejected dependent claims are allowable at least for the reasons stated above. Each of the dependent claims is further allowable in view of each claim’s unique and non-obvious combination of features.

VII. PTO-1449 Citations

The Examiner has requested the dates of publication and sources for two references included in the form PTO-1449 filed on March 9, 2004. The complete citation for one of these references is as follows:

Teramoto et al., "Phase transition for aqueous solution of polyelectrolyte complex containing N-isopropylamide," *Japanese Journal of Polymer Science and Technology* Vol. 54, pp. 477-482 (1997) (Abstract).

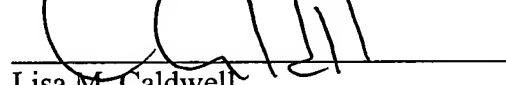
After an extensive investigation, a publication date was not found for the Hattori reference. A revised PTO-1449 is attached for the Examiner's signature.

If any further issues remain concerning this application, the Examiner is requested to call the undersigned.

Respectfully submitted,

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